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**DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION**

**[Docket No. 10-53]
KAMAL TIWARI, M.D.;
PAIN MANAGEMENT AND SURGERY
CENTER OF SOUTHERN INDIANA
DECISION AND ORDER**

On April 23, 2010, I, the Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Kamal Tiwari, M.D. (Respondent Tiwari), holder of DEA Certificate of Registration BT2936411, and his principal place of business, the Pain Management and Surgery Center (Respondent PMSC), holder of DEA Certificate of Registration BP4917413, both of Bloomington, Indiana. The Show Cause Order proposed the revocation of each Respondent's registration, on the ground that Respondent Tiwari had committed acts which render the continued registration of each Respondent "inconsistent with the public interest." Show Cause Order, at 1 (citing 21 U.S.C. §§ 823(f) and 824(a)(4)).

The Show Cause Order specifically alleged that between March 2003 and August 2008, Respondent Tiwari issued "numerous" prescriptions for controlled substances to three patients, who were addicts, and "who did not exhibit any verifiable medical indications warranting the prescribing of controlled substances." *Id.* at 2. The Order thus alleged that Respondent lacked a legitimate medical purpose and acted outside the usual course of professional practice in issuing the prescriptions and violated federal and state laws. *Id.* (citing 21 U.S.C. § 841(a)(1); 21 CFR 1306.04(a); Ind. Code § 25-1-9-4(a)(9)). With respect to these patients, the Show Cause Order further alleged that Respondent prescribed controlled substances to them "in exchange for their

agreements to undergo medical procedures . . . for profit,” and that “[t]his prescribing pattern indicates” that he issued the “prescriptions without a legitimate medical purpose and outside the scope of professional practice.” Id. at 2-3.

The Show Cause Order also alleged that a medical expert concluded that Respondent’s prescribing to these three patients lacked “a legitimate medical purpose and [was] outside the scope of professional practice.” Id. at 3. The Order further alleged that the expert concluded with respect to these three patients, as well as nine other patients, that Respondent’s “actions encouraged the abuse of controlled substances and allowed their misuse,” that his prescribing of controlled substances contributed to the deaths of six patients, and that there was no justification for his “long-term prescribing of controlled substances . . . or the administration of procedures using controlled substances” to these patients. Id.

Next, the Show Cause Order alleged that a second medical expert concluded that Respondent Tiwari had prescribed controlled substances to, and/or performed medical procedures using controlled substances without medical justification on, several other patients. Id. Finally, the Show Cause Order alleged that “at least nine of” Respondent’s patients had died over a six-year period, the most recent being in February 2009, and that Respondent had “continue[d] to prescribe controlled substances to patients at per-patient rates that [we]re similar to the prescribing rates in 2008, when two of [his] patients died of conditions related to drug abuse.” Id.

Based on the above, I concluded that Respondents’ continued registration during the pendency of the proceeding “constitutes an imminent danger to the public health and safety.” Id. at 4. I therefore ordered that each Respondent’s registration be immediately suspended. Id.

On May 24, 2010, Respondents filed a request for a hearing and the matter was assigned

to an Administrative Law Judge (ALJ), who proceeded to conduct pre-hearing procedures. However, on May 27, 2010, the Government moved for Summary Disposition and filed a Motion to Stay the Filing of Prehearing Statements. Mot. Summ. Disp., at 2-3.

The basis of the Government's motion was that each Respondent currently lacks authority to handle controlled substances in the State of Indiana, the jurisdiction where the Respondents are licensed to practice medicine and hold their DEA registrations. Mot. Summ. Disp., at 1-2 (citing 21 U.S.C. §§ 801(21), 823(f), 824(a)(3)). In support of its motion, the Government attached a letter from the Medical Licensing Board of Indiana (MLB) to Respondent Kamal Tiwari, dated May 26, 2010, stating that his Indiana controlled substance registration (CSR) Number 01034945B, had been suspended pursuant to Indiana Code § 35-48-3-5(e).¹ Id. at Ex. 3. The Government also attached a printout from the Indiana Online Licensing website which shows that Indiana CSR Number 61100223B, held by Respondent PMSC, has also been suspended. Id. at Ex. 4.

Thereafter, the ALJ issued an Order for Respondents' Response to Government's Motion for Summary Disposition and to Stay the Filing of Prehearing Statements; she also stayed the filing of the Prehearing statements. ALJ's Recommended Ruling (also ALJ), at 4.

On June 16, 2010, Respondents filed their Response. Therein, Respondents argued that granting summary disposition based on their lack of state authority to handle controlled substances would be circular and violate their right to Due Process, because the State's suspension of their state CSRs was based on the DEA Order to Show Cause and Immediate Suspension of Registration. Resps. Response at 1, 3-6. Respondents also argued that in suspending their state registrations, the MLB cited "no basis for the State suspension other than

¹ This provision states: "If the Drug Enforcement Administration terminates, denies, suspends or revokes a federal registration for the manufacture, distribution, or dispensing of controlled substances, a registration issued by the board under this chapter is **automatically** suspended." Ind. Code § 35-48-3-5(e).

the federal suspension.” Id. at 2. Respondents further maintain that the MLB “has no authority concerning controlled substances registrations, which are instead under the jurisdiction of the Indiana State Board of Pharmacy.” Id. at 2-3 (citations omitted).

Respondents also argued that in none of the cases cited by the Government did it “attempt to rely . . . on a derivative state action triggered by the Government’s suspension,” and that “[n]ot a single one of the Government’s cases revoke[d] a registration under 21 U.S.C. § 843(a)(3) without some independent determination” by the respective state authority. Id. at 4. Respondents thus maintained that “[d]epriving a practitioner of the right to review of a DEA action based solely on a State suspension that was in turn based solely on the original DEA action would violate Due Process.” Id. at 5. Finally, Respondents also contended that “[p]ractitioners may not be able to obtain review of either suspension, if the State takes the same position that the [DEA] does here.” Id.

On June 17, the Government filed its Reply to Opposition to Government’s Motion for Summary Disposition and to Stay the Filing of Pre-hearing Statements (Reply). The Government argued that “Indiana law specifically provides a basis for substantive review of any state suspension which is triggered by a DEA suspension.” Reply at 1 (citing Ind. Code § 35-48-3-5(f)).² The Government further argues that under DEA precedent, “when a state suspends a respondent’s controlled substance privileges, Federal revocation is warranted as long as the respondent has some mechanism to challenge the state action.” Id. at 2 (citing Odette Louise Campbell, M.D., No. 09-62, Order Remanding for Further Proceedings).³

² “The board may reinstate a registration that has been suspended under subsection (e), after a hearing, if the board is satisfied that the applicant is able to manufacture, distribute, or dispense controlled substances with reasonable skill and safety to the public.” Ind. Code § 35-48-3-5(f).

³ The Government also argued that “to the extent that Respondents argue that the Medical Licensing Board of Indiana . . . has no authority concerning controlled substance registrations, that jurisdictional argument must be made to the Board of Pharmacy,” and that in “its letter to [Respondent] Tiwari, the Medical Licensing Board . . .

On June 18, 2010, Respondents filed a Surreply in Opposition to Government's Motion for Summary Disposition (Surreply), in which they assert that the Government "fundamentally misunderstands the Indiana statutory scheme." Surreply, at 1. Therein, the Respondents again argued that the "Government's Motion for Summary Disposition should be denied because it relies on a potential, nonbinding state hearing, a theoretical possibility that cannot be triggered until the Indiana Board that actually has authority to suspend the Respondents' controlled substances registrations issues an order to show cause, which it has not." Id. Respondents further maintained that "the Indiana Advisory Committee could avoid the hearing provision on which the Government relies solely by not issuing the show cause notice." Id. at 2.

On June 21, 2010, the ALJ issued an Order for Government's Response to Surreply in Opposition to Government's Motion for Summary Disposition. On July 2, 2010, the Government filed its Response to Surreply. The Government reiterated that the Respondents' Indiana CSRs have been suspended and that while the issuance of the DEA Immediate Suspension Orders "may have been the cause of the state suspension, [they] do not govern whether those state suspensions remain in effect." Response to Surreply, at 1.

The Government again argued that under Indiana law, the Board of Pharmacy "may reinstate a [CSR] that has been suspended under subsection (e), after a hearing, if the board is satisfied that the applicant is able to . . . dispense controlled substances with reasonable skill and safety to the public." Id. (quoting Ind. Code § 35-48-3-5(f)). The Government also noted that Respondents had filed a Petition for Review of the state suspensions, albeit with the Medical Licensing Board and not the Board of Pharmacy. Id. The Government argued that this

merely informed Respondent that his CSR was suspended pursuant to the appropriate statute." Reply at 3. Finally, the Government attached a May 27, 2010 letter from the Indiana Board of Pharmacy to Respondents which stated that Indiana CSR Number 61100223B, which is held by Respondent PMSC, had been suspended pursuant to Ind. Code § 35-48-3-5(e). Reply at 3, Ex. 3-A.

nonetheless demonstrated that Respondents knew of, and were pursuing, their right to seek administrative review of the State's suspensions, pursuant to section 35-48-3-5(f).

Next, the Government argued that Respondents' contention that Indiana must issue an Order to Show Cause prior to suspending their CSRs is without merit, and that in any case, the issue is a matter of state law, and not a matter for a DEA ALJ to decide. Response to Surreply, at 2. Finally, the Government argued that the Respondents' interpretation of the Indiana statutes would render them inconsistent and meaningless. Id. at 2-3.

On July 7, 2010, the ALJ issued her recommended decision (hereinafter ALJ). Therein, the ALJ specifically found that the Indiana Board of Pharmacy had automatically suspended the Indiana CSRs held by the Respondents. ALJ at 5. Noting the settled Agency rule that "possessing authority under state law to handle controlled substances is an essential condition for holding a DEA registration," id. at 6 (quoting Joseph Baumstarck, M.D., 74 FR 17525, 17527 (2009)), and rejecting Respondents' contention that granting summary disposition would deny them their right to Due Process, the ALJ granted the Government's Motion for Summary Disposition. ALJ at 5-7, 9. The ALJ thus recommended that I revoke the Respondents' DEA Certificates of Registration and deny any pending applications to renew their registrations. Id. at 9.

Neither party filed exceptions to the ALJ's decision. Thereafter, the record was forwarded to me for final agency action.

Having considered the record as a whole including the parties' pleadings, I adopt the ALJ's findings of fact and recommended sanction. I will therefore revoke Respondents' respective DEA Certificates of Registration and deny any pending applications to renew their registrations. I make the following findings.

FINDINGS

Respondent Tiwari is the holder of Certificate of Registration BT2936411, which authorizes him to dispense controlled substances in schedules II through V, as a practitioner. While this registration was due to expire on November 30, 2009, on October 2, 2009, Respondent Tiwari submitted a timely renewal application. Respondent Tiwari's registration thus remains active, albeit in suspended status, pending the issuance of the Final Order in this matter. 5 U.S.C. § 558(c).

Respondent PMSC is the holder of Certificate of Registration BP4917413, which authorizes it to dispense controlled substances in schedules II through V, as a hospital/clinic. This registration is due to expire on March 31, 2011. According to the registration records of this Agency, Respondent Tiwari has also submitted an application to renew Respondent PMSC's registration.

On or about May 27, 2010, the Indiana Board of Pharmacy placed Respondent PMSC's Indiana CSR in suspended status. See Reply to Opp. to Gov. Mot. for Summ. Disp., at Ex. 3-A. Moreover, according to a letter from the MLB to Respondent Tiwari, on or about May 26, 2010, his Indiana CSR was placed in suspended status. Id. at Ex. 3. According to the Indiana Online Licensing website, of which I take official notice, each Respondent's CSR remains suspended as of the date of this Decision and Final Order.⁴

⁴ Under the Administrative Procedure Act (APA), an agency "may take official notice of facts at any stage in a proceeding-even in the final decision." U.S. Dept. of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is "entitled on timely request, to an opportunity to show to the contrary." 5 U.S.C. § 556(e); see also 21 CFR 1316.59(e). Respondent can dispute the facts of which I take official notice by filing a properly supported motion for reconsideration within twenty days of service of this Order, which shall begin on the date it is mailed.

DISCUSSION

Under the Controlled Substances Act (CSA), a practitioner must be currently authorized to handle controlled substances in “the jurisdiction in which he practices” in order to maintain a DEA registration. See 21 U.S.C. § 802(21) (“[t]he term ‘practitioner’ means a physician . . . pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice”). See also id. § 823(f) (“The Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.”). As these provisions make plain, possessing authority under state law to handle controlled substances is an essential condition for obtaining and maintaining a practitioner’s registration.

Accordingly, DEA has held that revocation of a practitioner’s registration is warranted whenever his (or its) state authority to dispense controlled substances has been suspended or revoked. David W. Wang, 72 FR 54297, 54298 (2007); Sheran Arden Yeates, 71 FR 39130, 39131 (2006); Dominick A. Ricci, 58 FR 51104, 51105 (1993); Bobby Watts, 53 FR 11919, 11920 (1988). See also 21 U.S.C. § 824(a)(3) (authorizing revocation of a registration “upon a finding that the registrant . . . has had his State license or registration suspended [or] revoked . . . and is no longer authorized by State law to engage in the . . . distribution [or] dispensing of controlled substances”).

DEA has further held that revocation is warranted even where a practitioner’s state authority has been summarily suspended and the State has yet to provide the practitioner with a hearing to challenge the State’s action and at which he (or it) may ultimately prevail. See Robert Wayne Mosier, 75 FR 49950 (2010) (“revocation is warranted . . . even in those instances where

a practitioner's state license has only been suspended, and there is the possibility of reinstatement"); accord Bourne Pharmacy, 72 FR 18273, 18274 (2007); Anne Lazar Thorn, 62 FR 12847 (1997).

Here, it is undisputed that the State has suspended the state controlled substance registration of each Respondent. DEA has long held that the order of a state agency suspending or revoking a practitioner's state authority cannot be collaterally attacked in a proceeding under the CSA. See Hicham K. Riba, 73 FR 75773, 75774 (2008) (rejecting claim that state proceeding was fundamentally unfair based on alleged improper ex parte influence of director of state board as "not addressable in" DEA proceeding); Sunil Bhasin, 72 FR at 5082, 5083 (2007) (rejecting claim that settlement agreement in which Respondent surrendered state license was produced by fraud and was unconscionable; "a DEA Show Cause Proceeding is not the proper forum to litigate the issue"); see also Shahid Musud Siddiqui, 61 FR 14818 (1996); Robert A. Leslie, 60 FR 14004 (1995).

The underlying premise of these cases is that the States exercise sovereign powers in regulating the medical profession and that challenges to the validity of state board orders should be raised and litigated in state forums. See, e.g., Riba, 73 FR at 75774 (claim that "state proceeding was fundamentally unfair . . . is not addressable in" DEA proceeding). These cases likewise implicitly recognize that state boards and state courts are fully cognizant of their obligation under the Due Process Clause to provide a full and fair opportunity to litigate the issues. Cf. University of Tennessee v. Elliott, 478 U.S. 788,797-98 (1986) ("When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata[.]") (int. quotations and citations omitted).

It is true that in Odette Louise Campbell, M.D., No. 09-62, I denied the Government's request for a final order based on the registrant's loss of her controlled substance prescribing authority under Texas law where the State had suspended that authority based on DEA's issuance of an immediate suspension order and remanded the matter for further proceedings. Campbell, Order Remanding for Further Proceedings, at 10-11. However, I noted that specific provisions of Texas law and regulations suggested that the registrant was not entitled to a hearing to challenge the merits of the state suspension because it was based on the DEA immediate suspension. Id. at 9 (citing Texas Health & Safety Code §§ 481.063(e)(3), 481.063(h), 481.066(g), and Tex. Admin. Code § 13.272(h)). Moreover, I ordered the ALJ to first determine whether the State had provided, or would provide, the registrant with a hearing; I further ordered that if the State had provided or would provide a hearing, the Government could renew its motion for summary disposition. Id. at 10.

By contrast, while the Indiana Board(s) suspended Respondents' state registrations based on the state law provision that "[i]f the Drug Enforcement Administration . . . suspends . . . a federal registration for the . . . dispensing of controlled substances, a registration issued by the board under this chapter is automatically suspended," Ind. Code § 35-48-3-5(e), state law further provides that "[t]he board may reinstate a registration that has been suspended under subsection(e) after a hearing, if the board is satisfied that the applicant is able to manufacture, distribute or dispense controlled substances with reasonable skill and safety to the public." Id. § 35-48-3-5(f). (emphasis added). Thus, it appears that Respondents are entitled to a hearing to challenge the underlying allegations before the State board.

Respondents contend that their right to a hearing under section 35-48-3-5(f) "is not triggered until the Indiana Controlled Substances Advisory Committee serves upon the ...

registrant an order to show cause why registration should not be denied, revoked or suspended,” and that “absent such a step, the purported suspension issued by the board . . . is a nullity, and cannot form the basis for a federal suspension.” Surreply at 2 (citing Ind. Code § 35-48-3-6(a)).⁵ Respondents further argue that “[i]f it could, then the Indiana Advisory Committee could avoid the hearing provision on which the Government relies solely by not issuing the show cause notice.” Id.

Beyond the fact that Respondents’ argument appears to be based on the speculative premise that the Indiana authorities will attempt to prevent them from obtaining a hearing, the Indiana statute makes clear that Respondents are entitled to a hearing. Presumably, the Indiana courts are open and can provide an appropriate remedy in the event the state board refuses to provide Respondents with a hearing. See Ind. Code § 34-27-3-1 (“An action for mandate may be prosecuted against any inferior tribunal, . . . public . . . officer, or person to compel the performance of any . . . act that the law specifically requires[.]”).

Moreover, the question of whether the Indiana suspensions are a nullity because the State did not serve Respondents with a Show Cause Order is an issue of state law and for the Indiana courts to decide. As such, it is outside the scope of this proceeding. See George S. Heath, M.D., 51 FR 26610 (1986) (“DEA accepts as valid and lawful the action of a state regulatory board unless that action is overturned by a state court or otherwise pursuant to state law. . . . The [DEA] will not consider a challenge to the lawfulness of a Georgia Board Order. Such a

⁵ This provision states:

Before recommending a denial, suspension, or revocation of a registration, or before refusing a renewal of registration, the board shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended The order to show cause shall contain a statement of the basis therefor [sic] and shall call upon the applicant or registrant to appear before the board at a time and place not less than thirty (30) days after the date of service of the order

challenge must be made in another forum.”); see also Shahid Musud Siddiqui, M.D., 61 FR 14818, 14818-19 (DEA 1996) (A “DEA administrative proceeding is not an appropriate forum for wholesale review of state criminal and administrative actions taken by the State of New York arising out of the laws of the State of New York. To allow it to be so would be to permit a wide collateral attack upon such convictions.”) (int. quotations and citation omitted).

Finally, Respondents argue that the suspensions of their state CSRs are invalid because they were suspended by the MLB and only the Pharmacy Board has authority under state law to suspend their registrations. However, the Pharmacy Board’s May 27, 2010 letter makes clear that it (and not the MLB) was suspending Respondent PMSC’s registration, and even if Respondent Tiwari’s controlled substance registration was suspended by the MLB, the validity of this action is also a question of state law and for the Indiana courts to decide. Riba, 73 FR at 75774; Heath, 51 FR at 26610.

Because there is no dispute over the material fact that each Respondent’s Indiana controlled substance registration has been suspended, each is without authority to hold a DEA registration.⁶ See 21 U.S.C. § 802(21). Accordingly, Respondents’ registrations will be revoked and any pending applications will be denied.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. §§ 823(f) and 824(a), as well as 28 CFR 0.100(b) and 0.104, I order that DEA Certificate of Registration, BT2936411, issued to Respondent Kamal Tiwari, M.D., and DEA Certificate of Registration, BP4917413, issued to

⁶ Where, as here, no material fact is in dispute, there is no need for an evidentiary hearing and summary disposition is appropriate. See Michael G. Dolin, M.D., 65 FR 5661 (2000); see also Philip E. Kirk, M.D., 48 FR 32887 (1983), aff’d sub nom Kirk v. Mullen, 749 F.2d 297 (6th Cir. 1984).

Respondent Pain Management and Surgery Center of Southern Indiana, be, and they hereby are, revoked. I further order that any pending applications of Kamal Tiwari, M.D. and Pain Management and Surgery Center of Southern Indiana, to renew or modify such registrations, be, and they hereby are, denied. This Order is effective immediately.⁷

Dated:
November 8, 2011

Michele M. Leonhart
Administrator

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⁷ For the same reason that I ordered that the Respondents' registration be immediately suspended, I conclude that the public interest necessitates that this Order be effective immediately. See 21 CFR 1316.67.